

REMARKS

The Office Action alleged that the claims lacked unity of invention and required election of a single species to which the claims will be restricted. In reply, the applicant elects *with traverse* the invention identified as Group I in the Office Action, *i.e.*, claims drawn to an aminated polysaccharide and a pharmaceutical composition thereof.

The applicants respectfully submit that the restriction of the claims for lack of unity of invention is improper. The applicant further submits that all the claims share the same special technical feature, namely aminated pneumococcus type 5 capsular polysaccharides described in claim 1.

As noted by the Examiner, a method of producing an aminated polysaccharide of Group I requires a reductive amination step. The Examiner then alleges that the aminated polysaccharide of Group I can be produced by a conventional reductive amination, such as selective hydrolysis or oxidative cleavage. When a conventional reductive amination method is performed on pneumococcus type 5 capsular polysaccharide, the Sug residue of the base unit of the pneumococcus type 5 polysaccharide is converted into three compounds. One of these compounds, compound X, is undesirable because it decreases the immunogenicity of the pneumococcus type 5 capsular polysaccharide (p. 7, lines 10-17). Pneumococcus type 5 capsular polysaccharide subject to conventional reductive animation manifests a ^{13}C NMR signal between 13 and 14 ppm, inclusive (p. 5, l. 37 – p. 6, l. 20) and/or a peak between fucosamine and pneumosamine in an HPAEC-PAD chromatogram obtained by elution from a CarbopacTM PA10 column in an 18 mM sodium hydroxide solution at a flow rate of 1 ml/min for 15 min of monosaccharides derived from hydrolysis of the conventionally reductively animated polysaccharide.

In the present invention, by contrast, the step of reductive amination is either (a) carried out under very specific conditions as it is claimed in claim 11 (*i.e.* duration of the reaction and pH conditions), or (b) associated with other chemical steps as it stands in claim 15. Contrary to conventional reductive amination methods, the processes in claims 11 and 15 produce the derivatives of pneumococcus type 5 capsular polysaccharides with substantially increased immunogenicity and, significantly, without substantial amounts of compound X (see Example 3,

Tables 1 and 2). Accordingly, a ^{13}C NMR signal between 13 and 14 ppm, inclusive, (p. 5, l. 37 – p. 6, l. 20) and/or a peak between fucosamine and pneumosamine in an HPAEC-PAD chromatogram obtained by elution from a CarbopacTM PA10 column in an 18 mM sodium hydroxide solution at a flow rate of 1 ml/min for 15 min of monosaccharides derived from hydrolysis of the conventionally reductively animated polysaccharide are not observed.

In brief, the product made by the process (Group I) and the process of making (Group II) are not distinct inventions, because the product cannot be made successfully by a materially different process. Therefore, the restriction under MPEP § 806.05(f) is improper.

In view of the foregoing amendments and remarks, the applicant submits that the claims are in condition for allowance, which is respectfully solicited. If the examiner believes a teleconference will advance prosecution, he is encouraged to contact the undersigned as indicated below.

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